



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/533,272

04/28/2005

Ian James Collins

T1599YP

7510

210 7590 03/17/2008  
MERCK AND CO., INC  
P O BOX 2000  
RAHWAY, NJ 07065-0907

EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,272	<b>Applicant(s)</b> COLLINS ET AL.	
	<b>Examiner</b> SUSANNAH CHUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-7 and 11 are pending in the instant application. Claims 8-10 are canceled.

#### ***Response to Non-Final Office Action***

Acknowledgment is made of applicant's response and amendment of the claims filed on 1/22/2008.

Claim 10 was rejected under 35 U.S.C. 112, first paragraph. This rejection is obviated because claim 10 is canceled.

Claims 1-7 and 10 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-16 of U.S. Patent Num. 7,041,689, Claims 1-6 of U.S. Patent Num. 7,138,400, and Claims 1-10 of U.S. Patent Num. 7,282,513. The rejection of claim 10 is obviated because it is canceled. The response to the rejection of claims 1-7 are addressed.

Claims 1-7 were rejected as being unpatentable over Claims 1-16 of U.S. Patent Num. 7,041,689. Applicant's arguments are acknowledged, but Examiner respectfully disagrees. With respect to the '689 Patent Applicant points out the following differences: (1) the prior art variable X cannot be pyrazole substituted with R1, while in the instant application it is; (2) the prior art variable R can be at any position of the X moiety, while in the instant application it is fixed; (3) the instant application contains an X variable not present in the prior art.

First, the prior art variable can be pyrazole. (See '689 Patent, Column 7, approx. lines 15-35.) The instant application claims R1, but R1 can be methyl. It is well known in the art that hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137.

Art Unit: 1626

Second, R can be a positional isomer of the instant application, but this is an obvious variation well known in the art. One of ordinary skill knows that positional isomerism has been used as a tool to obtain new and useful drugs. *In re Grabiak*, 226 USPQ 870. Further, adjacent homologues and structural isomers are generally so structurally similar that “without more” such structural similarity could give rise to prima facie obviousness. *In re Wilder*, 563 F.2d 457, 195 USPQ 426.

Third, the instant application contains an X variable, which can be OH or F. It is well known in the art that hydrogen and fluorine are bioisosteres. It is also well known that F and OH are bioisosteres. They contain properties that are so similar that they often substituted for each other. (See Patini, et al., *Chem. Rev.* 1996, 96, 3147-3176. Especially see page 3148, Table 2 Grimm’s hydride displacement law, wherein F and OH are interchangeable. Especially see page 3149, Table 4, wherein H and F are shown as classical bioisosteres.)

The differences that Applicant points to are all obvious to one of ordinary skill in the art. Absent a showing of unexpected results, the instantly claimed compounds are obvious in view of the teachings and claims of the ‘689 Patent. A timely filed terminal disclaimer will overcome this rejection.

Claims 1-7 were rejected as being unpatentable over Claims 1-6 of U.S. Patent Num. 7,138,400. This rejection is withdrawn because pyrazole as depicted in the specification in example 143 is not claimed.

Claims 1-7 were rejected as being unpatentable over Claims 1-10 of U.S. Patent Num. 7,282,513. Applicants point to the proviso in the instant application that R2 cannot be 2,2,2-trifluoroethyl and there is no substitution on the fused benzene ring (i.e. variable X). Applicants

Art Unit: 1626

arguments are acknowledged, but Examiner respectfully disagrees. The ODP rejection stands on the '513 Patent because as stated above, the variations, despite the proviso does not offer anything new and patentable. It would be clear to one of ordinary skill in the art that the variations off this complicated core are obvious (See above discussion, wherein it was shown that methyl v. hydrogen or hydrogen v. fluorine or fluorine v. hydroxyl or positional isomers are well known in the art.) A skilled artisan would be able to use the teachings of the '513 Patent and '689 Patent to make and use the instantly claimed compounds with obvious variations. The motivation is to produce compounds that have similar pharmaceutical activity and will be active in the same animal models. Therefore the ODP rejection stands over the '513 and '689 Patents. A timely filed terminal disclaimer will overcome these rejections.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem, Ph.D./  
Primary Examiner, Art Unit 1626

SLC, 3/3/2008